

LOCALIZATION OF A RADIOACTIVE SOURCE WITHIN A BODY OF A SUBJECT

RELATED APPLICATIONS

The present application claims the benefit under 35 USC 119(c) of U.S. Provisional Application No. 60/600,725 filed on August 12, 2004; entitled "Medical Navigation System Base on Differential Sensor"; 60/619,792 filed on October 19, 2004, entitled "Using a Catheter or Guidewire Tracking System", and 60/619,897 filed on October 19, 2004, entitled "Using a Radioactive Source as the Tracked.....", the disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to location and tracking of a source of ionizing radiation, for example within a body of a subject.

BACKGROUND OF THE INVENTION

Existing techniques for intrabody tracking include direct video imaging using a laparoscope; fluoroscopy (performance of the procedure under continuous or periodic X-Ray imaging); electromagnetic tracking, optical tracking, computerized tomography (CT) tracking and ultrasonic image assisted tracking. Some of these techniques explicitly avoid ionizing radiation. Those techniques which employ ionizing radiation, such as fluoroscopy and CT, require sufficient amounts of ionizing radiation that radiation exposure for subjects and medical staff is a subject of concern.

Some applications which require intrabody tracking, such as cardiac catheterization, require concurrently acquired images because the tissue through which the tracked medical device is being navigated moves frequently. Other applications which require intrabody tracking, such as intracranial procedures, are more amenable to the use of pre-acquired images because the relevant tissue is relatively static.

SUMMARY OF THE INVENTION

An aspect of some embodiments of the present invention relates to using ionizing radiation from a source in order to detect its position, optionally in or near the body of a subject, without production of an image. Optionally, the source is integrally formed with or attached to a medical device. Medical devices include, but are not limited to, tools, implants, navigational instruments and ducts.

In an exemplary embodiment of the invention, position of the source is determined by non-imaging data acquisition. For purposes of this specification and the accompanying claims, the phrase "non-imaging" indicates data acquired independent of an image acquisition process that includes the source and anatomical or other non-source features in a same image.

5 Optionally, position is determined using a sensor which has angular sensitivity resulting in a detectable change in output resulting from radiation detection according to an effective angle of incidence of radiation from the source. Greater sensitivity in effective angle of incidence provides greater efficiency of the position determination in terms of speed and accuracy. Embodiments with an angular range of less than ± 100 milliradians, optionally less
10 than ± 50 milliradians are disclosed. In an exemplary embodiment of the invention, greater sensitivity to effective angle of incidence can be achieved by moving a radiation detector and/or a shield.

Optionally, the source of ionizing radiation has an activity in the range of 0.01mCi to 0.5mCi. Optionally, the source of ionizing radiation has an activity less than 0.1 mCi.
15 Optionally, the source of ionizing radiation has an activity of about 0.05 mCi. In an exemplary embodiment of the invention, a radiation source which poses no significant health risk to a patient (i.e. short term exposure) and/or medical personnel (i.e. long term exposure) may be employed.

Optionally, the refresh rate for the location data insures that the locational information
20 is temporally well correlated to the actual location of a tracked object (e.g. medical device). Recommended refresh rates vary according to the speed at which the tracked object moves and according to the environment in which the tracked object moves. In an exemplary embodiment of the invention, for tracking of medical devices through body parts which are more static, such as brain or digestive tract, lower refresh rates, for example 10 times/second may be adequate.
25 In embodiments for tracking of medical devices through body parts which move frequently, such as the heart, higher refresh rates, for example 20 times/second may be desirable. Optionally, gating to an ECG output may be implemented so that positions from selected cardiac cycle phases are plotted.

Optionally, the RMS error of a calculated position of the source of ionizing radiation is
30 less than 10mm, optionally less than 5 mm, optionally less than 2 mm, optionally less than 1 mm, optionally 0.5 to 0.8 mm or better.

Variables which may influence the accuracy of determined position(s) include activity of the source in DPM, the accuracy and/or response time of radiation sensors employed for detection, and the speed of the implanted medical device. Improvement in one or more of these

variables may compensate for one or more other variables. Optionally, reducing the speed of a tracked medical device may be employed to compensate for other variables. Optionally, location information is displayed in the context of anatomical imaging data. Optionally, relevant anatomical features are highlighted to facilitate navigation of the medical device by medical personnel. Optionally, determined positions may be displayed in the context of a separately acquired image.

Optionally, two or more sources may be tracked concurrently. Optionally, multi-source tracking is used in determining orientation of an asymmetric medical device. Optionally, multi-source tracking is used in coordinating activity of two or more medical devices for a medical procedure.

An aspect of some embodiments of the present invention relates to using a sensor with angular sensitivity to detect a direction towards a source of ionizing radiation. Optionally, two or three or more directions are determined, either concurrently or successively, so that a position may be determined by calculating an intersection of the directions. If three or more directions are employed, the location may be expressed as a three dimensional position. Optionally, a direction is used to determine a plane in which the source resides.

Optionally, sensors for detection of radiation from the source achieve the desired angular sensitivity by rotation of at least a portion of the sensor about an axis through a rotation angle. For example, detectors or radiation shields may be rotated. Alternately or additionally, sensors may achieve the desired angular sensitivity by translational motion.

An aspect of some embodiments of the present invention relates to a sensor with an angular sensitivity which causes changes in an output signal from at least one radiation detector in response to an effective angle of incidence between the detector and a source. A target value of the output signal is achieved at an angle indicating the direction towards the source. The direction is optionally used to determine a plane in which the source resides.

Optionally the sensor may include more than one radiation detector, each radiation detector having a separate output signal. Optionally, one or more radiation shields may be employed to shield or shadow at least a portion of at least one of the radiation detectors from incident radiation. The degree of shielding changes as deviation from the angle indicating a direction towards the source occurs and the output signal varies according to the degree of shielding.

Optionally, multiple radiation shields are employed in concert to form a collimator. The radiation shields may be either parallel to one another or skewed inwards. Optionally, the multiple radiation shield, whether parallel or skewed, may be rotated.

Optionally, the deviation from target output is 1% of the output range per milliradian of angular displacement away from an angle indicating a direction towards the source. Optionally deviation in output indicates direction of deviation as well as magnitude of deviation. According to various embodiments of the invention, radiation detectors and/or radiation shields
5 may be displaced to impart angular sensitivity. This displacement may be rotational and/or translational.

An aspect of some embodiments of the present invention relates to a computerized system for locating a medical device, optionally within a body of a subject by using angular sensitivity of a sensor module to determine a direction. The sensor module measures incident
10 radiation on one or more radiation detectors. Incident radiation produces an output signal which is translated to directional information by the system.

An aspect of some embodiments of the invention relates to association of a source of ionizing radiation with a medical device to facilitate determination of a location of the device, optionally as the device is navigated within or near a subject's body during a medical
15 procedure. Optionally, the source of ionizing radiation has an activity in the range of 0.01 mCi to 0.5 mCi. Optionally, the source of ionizing radiation has an activity less than 0.1 mCi. Optionally, the source of ionizing radiation has an activity of about 0.05 mCi. Association includes integrally forming the source and the device as a single unit. Association also includes attaching the source to the device. Optionally, the source is concentrated in an area having a
20 largest dimension less than 10 mm, optionally less than 5 mm, optionally less than 2.5 mm, optionally less than 1 mm.

An aspect of some embodiments of the invention relates to use of an ionizing radiation source with an activity of 0.1 mCi or less as a target for non imaging localization or tracking, optionally in a medical context. The source of ionizing radiation is selected to reduce a
25 biological effect on the patient and/or medical personnel. This selection involves consideration of radiation strength, radiation type and/or amount of exposure time (e.g. time in the body for a patient undergoing a procedure). Alternatively or additionally, radiation sources which are constructed of biocompatible material and/or coated with biocompatible coatings may be employed.

30 In an exemplary embodiment of the invention, a computerized system for tracking and locating a source of ionizing radiation is provided. The system comprising:

(a) at least one non-imaging sensor module comprising at least one radiation detector, the at least one radiation detector capable of receiving ionizing radiation from the radiation source and producing an output signal; and

(b) the CPU designed and configured to receive the output signal and translate the output signal to directional information.

Optionally, the source of radiation is integrally formed with or attached to a medical device.

5 Optionally, the at least one sensor module includes at least two sensor modules.

Optionally, the at least two sensor modules includes at least three sensor modules.

Optionally, the at least one of the at least one sensor module further comprises a locomotion device capable of imparting translational motion to the sensor module so that the sensor module is moved to a new location.

10 Optionally, the locomotion device is operable by a translational motion signal from the CPU.

Optionally, the system additionally comprises an imaging module, the imaging module capable of providing an image signal to the CPU, the CPU capable of translating the image signal to an image of a portion of the body of the subject.

15 Optionally, the system further comprises a display device.

Optionally, the display device is capable of displaying the image of the portion of the body of the subject with a determined position of the medical device superimposed on the image of the portion of the body of the subject.

20 Optionally, the CPU receives at least two of the output signals and computes a position of the radiation source based on the output signals.

Optionally, the CPU receives at least three of the output signals and computes a position of the radiation source based on the at least three output signals.

Optionally, wherein the CPU computes the position repeatedly at intervals so that a position of the radiation source as a function of time may be plotted.

25 Optionally, wherein the radiation source employs an isotope with a half life in the range of 6 to 18 months.

Optionally, the system further comprises additionally comprising the radiation source capable of providing the radiation.

30 Optionally, the directional information is produced when the source has an activity in the range of 0.01mCi to 0.5mCi.

In an exemplary embodiment of the invention, a sensor for directionally locating an ionizing radiation source is provided. The sensor comprises:

(a) at least one functional component; and

(b) a displacement mechanism which imparts angular sensitivity to the sensor by moving the at least one functional component.

Optionally, the at least one functional component comprising at least one radiation detector, the at least one radiation detector capable of receiving radiation from the radiation source and producing an output signal;

wherein the displacement mechanism is capable of rotating the at least one radiation detector through a rotation angle so that the output signal varies with the rotation angle.

Optionally, the at least one radiation detector comprises at least one first radiation detector and at least one second radiation detector and the output signal comprises at least one first output signal from the at least one first radiation detector and at least one second output signal from the at least one second radiation detector.

Optionally, the sensor comprises at least one radiation shield installed at a fixed angle with respect to the at least one first radiation detector and the at least one second radiation detector so that a magnitude of the first output signal from the at least one first radiation detector and a magnitude of the second output signal from the second radiation detector vary with the rotation angle.

Optionally, the sensor comprises:

(a) at least one first radiation detector and at least one second radiation detector, each of the at least one first radiation detector and at least one second radiation detector capable of receiving radiation from the radiation source and producing at least one first output signal from the at least one first radiation detector and at least one second output signal from the at least one second radiation detector;

(b) at least one radiation shield, the radiation shield rotatable about an axis of shield rotation through an angle of shield rotation, so that a magnitude of the first output signal from the at least one first radiation detector and a magnitude of the second output signal from the second radiation detector each vary with the angle of shield rotation.

Optionally, the at least one radiation shield comprises:

(i) a primary radiation shield located between the at least one first radiation detector and the at least one second radiation detector;

(ii) at least one first additional radiation shield deployed to interfere with incident radiation directed towards the at least one first radiation detector; and

(iii) at least one second additional radiation shield deployed to interfere with incident radiation directed towards the at least one second radiation detector.

Optionally, wherein the at least one first additional radiation shield and the at least one second additional radiation shield are each inclined towards the primary radiation shield.

Optionally, wherein the at least one first radiation detector and the at least one second radiation detector are organized in pairs, each pair having a first member and a second member and each radiation shield of the primary and additional radiation shields is located between one of the first member and one of the second member of one of the pairs so that the output signal varies with the rotation angle.

Optionally, the sensor is additionally capable of revolving the at least a functional component about an axis of revolution through an angle of revolution.

10 In an exemplary embodiment of the invention, a method of determining a location of a device is provided. The method comprises:

- (a) providing a device having a radiation source associated therewith;
- (b) determining a direction towards the radiation source;
- (c) further determining at least a second direction towards the radiation source;
- 15 (d) locate the device by calculating an intersection of the first direction and the at least a second direction.

Optionally, the further determining at least a second direction towards the radiation source includes determining at least a third direction towards the radiation source and additionally comprising:

- 20 (e) calculating a point of intersection of the first direction, the second direction and the at least a third direction.

In an exemplary embodiment of the invention, a method of manufacturing a trackable medical device is provided. The method comprises incorporating into or fixedly attaching a detectable amount of a radioactive isotope to the medical device.

25 Optionally, the detectable amount is in the range of 0.01mCi to 0.5mCi.

Optionally, the detectable amount is 0.1 mCi or less.

Optionally, the detectable amount is 0.05 mCi or less.

Optionally, the isotope is Iridium-192.

30 An aspect of some embodiments of the invention relates to use of an ionizing radiation source with an activity of 0.1 mCi or less as a target for non imaging localization or tracking.

BRIEF DESCRIPTION OF FIGURES

In the Figures, identical structures, elements or parts that appear in more than one Figure are generally labeled with the same numeral in all the Figures in which they appear.

Dimensions of components and features shown in the Figures are chosen for convenience and clarity of presentation and are not necessarily shown to scale. The Figures are listed below.

Fig. 1 is a side view of one embodiment of a sensor module according to an exemplary embodiment of the present invention;

5 Fig. 2 is a schematic representation of a computerized tracking system according to an exemplary embodiment of the present invention;

Fig. 3 is a side view of an additional embodiment of a sensor module according to an exemplary embodiment of the present invention illustrating receipt of a signal by the module;

10 Fig. 4 is a perspective view of a computerized tracking system according to an exemplary embodiment of the present invention illustrating one possible arrangement of sensor modules with respect to a patient;

Fig. 5 is a side view of another additional embodiment of a sensor module according to an exemplary embodiment of the present invention;

15 Figs. 6A and 6B are side views of further additional embodiments of a sensor module according to exemplary embodiments of the present invention;

Figs. 7A and 7B are graphs of simulated response time and simulated rms position error respectively plotted as a function of sensor rotation per photon impact using a system according to an exemplary embodiment of the present invention;

20 Figs. 8A and 8B are graphs of simulated response time and simulated rms position error respectively plotted as a function of sampling time using a system according to an exemplary embodiment of the present invention;

Figs. 9A and 9B are graphs of simulated response time and simulated rms position error respectively plotted as a function of specific activity of a radioactive signal source using a system according to an exemplary embodiment of the present invention;

25 Fig. 10A is a graph of position as a function of time. Simulated position output from a system according to an exemplary embodiment of the present invention is overlaid on a plot of actual input position for the simulation;

Fig. 10B is a graph of rms position error plotted as a function of time based upon the two plots of Fig. 10A;

30 Fig. 11 is a simplified flow diagram of a method according to exemplary embodiments of the present invention; and

Fig. 12 is a graph of sensor output as a function of rotation angle.

DETAILED DESCRIPTION OF EMBODIMENTS

According to one embodiment of the invention (Figures 2 and 4), a computerized system 40 locates and/or tracks a device. In the embodiment depicted in Figure 4, the device is a medical device. Medical devices include, but are not limited to, tools, implants, navigational instruments and ducts. Tools include, but are not limited to, catheters, canulae, trocar, cutting implements, grasping implements and positioning implements. Implants include, but are not limited to, brachytherapy seeds, stents and sustained release medication packets. Navigational instruments include, but are not limited to, guidewires. Ducts include, but are not limited to, tubing (e.g. esophageal tubes and tracheal tubes). In exemplary embodiments of the invention, one or more moving tools are tracked.

In an exemplary embodiment of the invention, position of the source is determined by non-imaging data acquisition. For purposes of this specification and the accompanying claims, the phrase "non-imaging" indicates data not acquired as part of an image acquisition process that includes the source and anatomical or other non-source features in a same image. Optionally, a sensor which is not suitable for and not connected to imaging circuitry is employed. Imaging relies upon information about many points, including at least one point of interest, and image analysis of the information determines characteristics of the point(s) of interest, for example position relative to an object. In an exemplary embodiment of the invention, position sensing provides information only about the source. This can improve detectability and/or accuracy.

Optionally, the medical device is at least partially within a body of a subject 54 during at least part of the path upon which its location is determined. In Figure 4, an exemplary embodiment in which system 40 is configured to track a device through the head of subject 54 during an intracranial medical procedure is depicted. This drawing is purely illustrative and should not be construed as a limitation of the scope of the invention.

Figure 2 shows an embodiment of system 40 including three sensor modules 20 which rely on angular detection acting in concert to determine a location of radioactive source 38. In the pictured embodiment, each of sensors 20 determines an angle of rotation 32 indicating a direction towards source 38. This angle of rotation 32 (Figure 1) defines a plane in which source 38 resides and which crosses radiation detector 22. Angle of rotation 32 is provided as an output signal 34 which is relayed to computerized processing unit (CPU) 42. CPU 42 determines an intersection of the three directions (planes) which is expressed as a point.

According to some embodiments of the invention, a source 38 located within the boundaries 24 of detection (Figure 1) of sensor 20 may be accurately located by system 40 as

radiation detector 22 of sensor module 20 is rotated through a series of rotation angles 32. A source 38 located outside of boundaries 24 will not be accurately located. For this reason, it is desirable, in some embodiments, that each of sensors 20 is deployed so that the predicted path of source 38 lies within boundaries 24. According to some embodiments of the invention, sensor 20 may move to keep source 38 within boundaries 24. The size and shape of boundaries 24 vary according to the configuration of sensor 20.

Accuracy of determination of target rotation angle 32 contributes to accuracy of the location of source 38 as determined by system 40. Various modifications to sensor module 20 which can increase the sensitivity to small differences in rotation angle 32 are depicted as exemplary embodiments in Figures 3, 5, 6A and 6B and explained in greater detail hereinbelow.

Figure 4 provides a perspective view of an exemplary system 40 which employs angular detection and includes three sensor modules 20 dispersed upon the circumference of a circle 58. In the pictured embodiment, modules 20 feature radiation shields 36. In the pictured embodiment, each module 20 rotates about an axis tangent to circle 58. This rotation allows tracking of the medical device as explained in greater detail hereinbelow. According to various embodiments of the invention, rotational motion or translational motion may be employed to facilitate the desired angular detection. According to the embodiment depicted in Figure 4, sensor modules 20 are situated below the head of subject 54 such that the vertical distance between the plane of sensor modules 20 and the region of interest within the head is approximately equal to the radius of circle 58. This arrangement assures that each of sensors 20 are deployed so that the predicted path of source 38 lies within boundaries 24. This arrangement may be repeatably and easily achieved by providing three of sensors 20 mounted on a board equipped with a raised headrest in the center of circle 58. This optionally permits a reclining chair or adjustable examination table to be easily positioned so that subject 54 is correctly placed relative to sensors 20 without an extensive measuring procedure.

Positioning volume of system 40 is the set of spatial coordinates in which a location of source 38 may be determined. Positioning volume of system 40 has a size and/or shape dependent upon positions of sensor(s) 20, their design and/or their performance characteristics. Optionally, positioning volume of system 40 can be expressed as the intersection of boundaries of detection 24 of sensors 20. Optionally, two or more positioning volumes may be created, by using multiple sets of sensors 20. Optionally, these positioning volumes may overlap.

The 3-dimensional position of the center of mass of a radiation source 38 is calculated by CPU 42 from the angle 32 measured by each of sensor modules 20, given the known

location and rotation axis of each of modules 20. According to some embodiments of the invention, source 38 will be a piece of wire with a length of 1 to 10 mm. This range of lengths reflects currently available solid isotope sources 38 supplied as wires with useful diameters and capable of providing a sufficient number of DPM to allow efficient operation of system 40.

5 System 40 determines the position of the middle of this piece of wire 38 and resolves the determined position to a single point, optionally indicating margins of error.

Sensor module 20 includes at least one radiation detector 22. Radiation detector 22 is capable of receiving radiation from radiation source 38 attached to the medical device and producing an output signal 34. Radiation detector 22 may employ any technology which
10 transforms incident radiation into a signal which can be relayed to CPU 42. If source 38 is a gamma radiation source, radiation detector 22 may be, for example, an ionization chamber, a Geiger-Mueller Counter, a scintillation detector, a semiconductor diode detector, a proportion counter or a micro channel plate based detector. Radiation detectors 22 of various types are commercially available from, for example, EVproducts (Saxonburg PA, USA); Hamamatsu
15 Photonics (Hamamatsu City, Shizuoka, Japan); Constellation Technology, (Largo, FL, USA); Soltec Corporation (San Fernando CA, USA); Thermo Electron Corporation, (Waltham MA, USA); Bruker-biosciences (Billerica MA, USA); Saint Gobain crystals (Newbury OH, USA) and Silicon Sensor GmbH (Germany). A suitable commercially available radiation detector 22 can be incorporated into the context of system 40 as part of sensor 20. Embodiments of the
20 invention which rely upon a source 38 producing a small number of DPM and S types of detectors 22 which offer good sensitivity (i.e. high ratio between CPM and DPM) will improve the performance of sensor modules 20. As the distance between sensor 20 and source 38 increases, this consideration becomes more relevant. Embodiments of the invention which rely upon source 38 with a greater DPM output may permit use of less sensitive radiation detectors
25 22.

Various types of sensor modules 20 are described in greater detail hereinbelow.

System 40 further includes radiation source 38 capable of providing a sufficient amount of radiation for location and/or tracking at a rate which will not adversely affect a procedure being carried out by the medical device. For most medical procedures, 10 locations/second is
30 sufficient to allow an operator of system 40 to comfortably navigate the medical device to a desired location. Based upon results from a computerized simulation described in greater detail hereinbelow, the amount of radiation to meet these criteria can be made low enough that it does not pose any significant risk to a patient undergoing a procedure of several hours duration with source 38 inside their body. Alternatively or additionally, the amount may be made low enough

so that an operator of system 40 is not exposed to any significant risk from radiation exposure over time as explained hereinbelow.

For example, using Iridium-192 increasing the activity of radiation source 38 from 0.01mCi to 0.5mCi improves accuracy only by a factor of 2 (Figure 9B). However, activity levels below 0.1 mCi adversely affect response time (Figure 9A). Activities greater than 0.1mCi do not significantly improve response time. An activity of 0.05 mCi offers an acceptable trade-off between latency and accuracy as described in greater detail hereinbelow and provides a good compromise between performance and radiation dose.

A 0.05 mCi source 38 meets permits system 40 to achieve adequate speed and accuracy with an amount of radiation produced so low that it may be safely handled without gloves. Radiation exposure for the patient from a 0.05 mCi source 38 is only eight times greater than average absorbed background radiation in the United States. For purposes of comparison to previously available alternatives, a 0.05 mCi source 38 exposes the patient to an Effective Dose Equivalent (EDE) of 0.0022 mSv/hr. A typical fluoroscopy guided procedure has an EDE of 1-35 mSV per procedure and a typical Nuclear Medicine procedure has an EDE of 5 mSv. Thus, some embodiments of the invention may be employed to significantly reduce patient radiation exposure.

Medical personnel are optionally exposed to even less radiation, with the level of exposure decreasing in proportion to the square of the intervening distance. For example, a doctor located one meter from a 0.05 mCi source 38 and performing procedures for 6 hours per day, 5 days a week, 52 weeks a year would accumulate a total annual EDE of 0.22 mSv. This is approximately 5% of the radiation exposure level at which exposure monitoring is generally implemented. This level of exposure corresponds to $1.4e^{-4}$ mSV/hr which is orders of magnitude less than the 1-12 mSv/hr associated with a typical dose from fluoroscopic procedures.

Iridium-192 has been used as an example because it is already approved for use in medical applications and is generally considered safe to introduce into the body of a subject. However this isotope is only an illustrative example of a suitable source 38, and should not be construed as a limitation of system 40. When choosing an isotope for use in the context of system 40, activity (DPM), type of radiation and/or half life may be considered. Activity has been discussed above. In addition, it is generally desired that disintegration events be detectable with reasonable efficiency at the relevant distance, for example 20-50 cm. Long half lives may be preferred because they make inventory control easier and reduce total costs in the

long run by reducing waste. However, short half lives may reduce concerns over radioactive materials and/or may allow smaller sources to be used.

According to some embodiments of the invention, source 38 is a source of positron emissions. According to these embodiments, sensors 20 determine a direction from which photons released as a result of positron/electron collisions originate. This difference optionally does not affect accuracy of a determined location to any significant degree because the distance traveled by a positron away from source 38 before it meets an electron is generally very small. Use of positrons in source 38 can effectively amplify total ionizing radiation emissions available for detection. Optionally, the use of multiple detector may allow the detection of pairs of positron annihilation events to be detected. Other examples of source types include gamma sources, alpha sources, electron sources and neutron sources.

Regardless of the isotope, source 38 may be incorporated into a medical device (e.g. guidewire or catheter) which is to be tracked. Incorporation may be, for example, at or near the guidewire tip and/or at a different location in a catheter or in an implant. The source of ionizing radiation may be integrally formed with, or attached to, a portion of the guidewire or to a portion of the medical device. Attachment may be achieved, for example by gluing, welding or insertion of the source into a dedicated receptacle on the device. Attachment may also be achieved by supplying the source as an adhesive tag (e.g. a crack and peel sticker), paint or glue applicable to the medical device. Optionally, the source of ionizing radiation is supplied as a solid, for example a length of wire including a radioactive isotope. A short piece of wire containing the desired isotope may be affixed to the guidewire or medical device. This results in co-localization of the medical device and the source of radiation. Affixation may be accomplished, for example, by co-extruding the solid source with the guidewire during the manufacture of the guide wire. Alternately, or additionally, the source of ionizing radiation may be supplied as a radioactive paint which can be applied to the medical device and/or the guidewire. Regardless of the exact form in which the ionizing radiation source is supplied, or affixed to the guidewire or medical device, it should not leave any significant radioactive residue in the body of the subject after removal from the body at the end of a medical procedure.

While source 38 is illustrated as a single item for clarity, two or more sources 38 may be tracked concurrently by system 40. System 40 may identify multiple sources 38 by a variety of means including, but not limited to, discrete position or path, frequency of radiation, energy of radiation or type of radiation. According to some embodiments of the invention, use of two or more resolvable sources 38 provides orientation information about the item being tracked. In

other words, these embodiments permit determination of not only a 3-dimensional position defined by co-ordinates X, Y and Z, but also information about the orientation of the tracked object at the defined location. This feature is relevant in a medical context when a non-symmetrical tool is employed.

5 System 40 may include a channel of communication 48 capable of conveying a data signal between the one or more sensor modules 20 and a computerized processing unit (CPU) 42. Channel of communication may be wired or wireless or a combination thereof. Wired channels of communication include, but are not limited to direct cable connection, telephone connection via public switched telephone network (PSTN), fiber optic connection and
10 construction of system 40 as an integrated physical unit with no externally apparent wires. Wireless channels of communication include, but are not limited to infrared transmission, radio frequency transmission, cellular telephone transmission and satellite mediated communication. The exact nature of channel of communication 48 is not central to operation of system 40 so long as signal transmission permits the desired refresh rate. Channels of communication 48
15 may optionally permit system 40 to be operated in the context of telemedicine. Alternately, or additionally, channels of communication 48 may serve to increase the distance between source 38 and medical personnel as a means of reducing radiation exposure to the medical personnel to a desired degree.

CPU 42 is designed and configured to receive output signal 34 via channel of
20 communication 48 and translate output signal 34 to directional information concerning radiation source 38. This directional information may be expressed as, for example, a plane in which radiation source 38 resides. Output signal 34 includes at least rotation angle 32. Optionally, output signal 34 may also include a signal strength indicating component indicating receipt of a signal from source 38. Receipt of a signal from source 38 may be indicated as
25 either a binary signal (yes/no) or a signal magnitude (e.g. counts per minute). According to various embodiments of the invention, output signal 34 may be either digital or analog. Translation of an analog signal to a digital signal may be performed either by sensor module 20 or CPU 42. In some cases, locating radiation source 38 in a single plane is sufficient. However, in most embodiments of the invention, it is desirable that CPU 42 receives two of output
30 signals 34 and computes an intersection. If output signals 34 are expressed as planes, this produces a linear intersection 44 of two of the planes. This locates radiation source 38 upon the linear intersection 44. Optionally, results 44 of this calculation are displayed on a display device 43 as described in greater detail hereinbelow. In additional embodiments of the invention, CPU 42 receives at least three of output signals 34 and computes their intersection.

If output signals 34 are expressed as planes and sensors 20 are positioned on the circumference of circle 58, this produces a point of intersection 44 of at least three planes, thereby locating radiation source 38 at the calculated point of intersection 44.

Because system 40 is most often employed to track a medical instrument during a medical procedure, CPU 42 is often employed to compute the point of intersection repeatedly at predetermined intervals so that a position of radiation source 38 as a function of time may be plotted (see Figure 10 a). The accuracy of each plotted position and of the plot as a whole may be influenced by the activity of source 38, the accuracy and response time of sensors 20 and the speed at which the implanted medical device is moving through subject 54. Because medical procedures generally favor precision over speed, an operator of system 40 may compensate for deficiencies in source 38, or accuracy or response time of sensors 20, by reducing the rate of travel of the medical device being employed for the procedure. Figure 10B illustrates output of a simulated system 40 with tracking accuracy in the range of ± 2 mm. CPU 42 may also optionally employ channel of communication 48 to send various signals to sensor module(s) 20 as detailed hereinbelow. Alternately, or additionally, CPU 42 may also optionally employ channel of communication 48 to send various signals to the medical device. According to various embodiments of the invention, system 40 may be employed in the context of procedures including, but not limited to, angioplasty (e.g. balloon angioplasty), deployment procedures (e.g. stent placement or implantation of radioactive seeds for brachytherapy), biopsy procedures, excision procedures and ablation procedures.

While CPU 42 is depicted as a single physical unit, a greater number of physically distinct CPUs might actually be employed in some embodiments of the invention. For example, some functions, or portions of functions, ascribed to CPU 42 might be performed by processors installed in sensor modules 20. For purposes of this specification and the accompanying claims, a plurality of processors acting in concert to locate source 38 as described herein should be viewed collectively as CPU 42.

According to some embodiments of the invention, system 40 concurrently employs three or more sensor modules 20 in order to concurrently receive three or more output signals 34 and compute three or more directions indicating signal source 38. If the directions are expressed as planes, the three or more planes intersect in a single point. However, system 40 includes alternate embodiments which employ two, or even one, sensor module 20 to localize source 38 to a single point. This may be achieved in several different ways as described hereinbelow.

According to some embodiments of system 40 at least one of sensor module 20 is capable of rotating the at least one radiation detector 22 through a series of positions. Each position is defined by a rotation angle 32 so that receiving the radiation from source 38 upon detector 22 varies with rotation angle 32. This rotation may be accomplished in a variety of ways. For example, rotation mechanism 26 may be operated by feedback from 28 from radiation detector 22 according to a rule with amount of received radiation as a variable. Alternately, rotation mechanism 26 may be operated by a signal from CPU 42 according to a rule including amount of received radiation and/or time as variables. Alternately, rotation mechanism 26 may rotate radiation detector 22 according to a fixed schedule, with no regard to how much radiation impinges upon radiation detector 22 at any particular rotation angle 32. Rotation mechanism 26 may employ a wide variety of different mechanisms for achieving rotation angle 32. These mechanisms include, but are not limited to, mechanical mechanisms, hydraulic mechanisms, pneumatic mechanisms, electric mechanisms, electronic mechanisms and piezoelectric mechanisms. Optionally, an independent angle measuring element 30 may be employed to more accurately ascertain the actual rotation angle 32. Although angle measuring element 30 is depicted as a physically distinct component in Figures 1, 2 and 3, it could be physically integrated into rotation mechanism 26 without affecting performance of system 40 to any significant degree. Regardless of the exact operational details, the objective is to detect the rotation angle 32 at which sensor module 20 is pointing directly towards source 38. This angle will be referred to as the target rotation angle 32.

According to some embodiments of system 40, radiation detector 22 (Figures 3, 5, 6A and 6B) includes at least one first radiation detector 22A and at least one second radiation detector 22B. These embodiments of system 40 rely upon comparison of output signals 34 from radiation detectors 22A and 22B for each rotation angle 32. A target angle of rotation 32 which produces output signals 34 from radiation detectors 22A and 22B with a known relationship indicates that radiation detectors 22A and 22B are both facing source 38 to the same degree. When radiation detectors 22A and 22B have identical receiving areas, the known relationship is equality. This target angle of rotation 32 is employed to determine a plane in which source 38 resides.

In order to increase the sensitivity of system 40 to small differences between output signals 34 from radiation detectors 22A and 22B it is possible to introduce one or more radiation shields 36 at a fixed angle with respect to radiation detectors 22A and 22B. Radiation Shield 36 causes a magnitude of the component of output signal 34 from first radiation detector 22A and a magnitude of the component of output signal 34 from second radiation detector 22B

to each vary with rotation angle 32 (see Figure 3). Radiation shield 36 differentially shadows either radiation detectors 22A or 22B depending upon the relationship between angles of incidence 39 and 41. At some angle of rotation 32, neither radiation detector 22A nor 22B will be shadowed by radiation shield 36. This angle of rotation 32 is employed to determine a plane in which source 38 resides. This configuration insures that small variations from this target angle of rotation 32 cause relatively large differences in the output signals 34 from radiation detectors 22A and 22B because of the shadow effect. Therefore, use of radiation shield 36 in sensor module 20 increases the sensitivity of system 40. This increased sensitivity permits sensor module 20 to function effectively even with a low number of detectable radioactive counts.

Figure 6A illustrates an additional embodiment of sensor module 20 in which the radiation shield includes a primary radiation shield 36 located between first radiation detector 22A and second radiation detector 22B. The pictured embodiment also includes a series of first additional radiation shields (36A1, 36A2, and 36A3) which divide first radiation detector 22A into a series of first radiation detectors and interfere with incident radiation directed towards first radiation detector 22A. The pictured embodiment also includes a series of second additional radiation shields (36B1, 36B2, and 36B3) which divide second radiation detector 22B into a series of second radiation detectors and interfere with incident radiation directed towards second radiation detector 22B. This configuration can insure that even smaller variations from target rotation angle 32 cause relatively large differences in the output signals 34 from radiation detectors 22A and 22B by increasing the shadow effect in proportion to the number of additional radiation shields (36A1, 36A2, 36A3, 36B1, 36B2, and 36B3 in the pictured embodiment). Therefore, use of additional radiation shields (e.g. 36A1, 36A2, 36A3, 36B1, 36B2, and 36B3) in sensor module 20 may serve to achieve an additional increase in sensitivity of system 40. Optionally, secondary radiation shields (36A1, 36A2, 36A3, 36B1, 36B2, and 36B3 in the pictured embodiment) are inclined towards primary radiation shield 36. The angle of secondary radiation shields 36A1, 36A2, 36A3, 36B1, 36B2, and 36B3 towards primary shield 36 can be changed, for example, using a motor to improve focus and/or define imaging volume.

A similar effect may be achieved by holding radiation detectors 22A and 22B at a fixed angle and subjecting radiation shield(s) 36 (Figure 6B) to angular displacement. Therefore, system 40 also includes embodiments in which radiation detector 22 includes at least one first radiation detector 22A and at least one second radiation detector 22B and output signal 34 includes discrete components from detectors 22A and 22B with at least one radiation shield 36

rotatable about an axis of shield rotation through an angle of shield rotation 32 so that a magnitude of discrete components of output signal 34 from detectors 22A and 22B each vary as a function of the angle of shield rotation 32.

Referring now to Figure 5, alternate embodiments of sensor module 20 of system 40 are configured so that radiation detector 22 includes a plurality of radiation detectors 22 and a plurality of protruding radiation shields 36 interspersed between the plurality of radiation detectors 22. According to these embodiments, plurality of radiation detectors 22 is organized in pairs, each pair having a first member 21 and a second member 23 and each protruding radiation shield 36 of the plurality of protruding radiation shields is located between first member 21 and second member 23 of the pair of radiation detectors 22. According to this embodiment, sensor module 20 is capable of rotating the radiation detectors 22 through a series of rotation angles 32 so that the receiving the radiation from radiation source 38 upon radiation detectors 22 varies with rotation angle 32. Each radiation detector produces an output signal 34. CPU 42 sums output signals 34 from all first members 21 to produce a first sum and all second members 23 to produce a second sum. Assuming that all of radiation detectors 22 are identical, when the sensor is aimed directly at the center of mass of source 38 (target rotation angle 32), the first sum and the second sum are equivalent. This embodiment insures that the total output for the entire module 20 increases rapidly with even a very slight change in rotation angle 32 in either direction. Alternately, or additionally, the sign of the total output for the entire module 20 indicates the direction of rotation required to reach the desired rotation angle 32 at which total output for the entire module 20. Thus, this configuration serves to increase both speed of operation and overall accuracy of system 40. This type of sensor module 20 may be operated (for example) by implementation of a first algorithm summing gamma ray impacts from source 38 for a period of time and allowing CPU 42 to decide, based on the sign of total output for the entire module 20, in which direction and to what degree to rotate radiation detectors 22 in an effort to reach a desired rotation angle 32. Alternately, CPU 42 may (for example) implement a second algorithm rotates radiation detectors 22 a very small amount in response to every detected count. Performance data presented herein is based upon a simulation of the second algorithm, but the first algorithm is believed to be equally useful.

According to additional embodiments of system 40, a single sensor module 20 may be employed to determine two intersecting planes in which source 38 resides. This may be achieved, for example, by revolution of sensor module 20 or by moving sensor module 20 to a new location.

According to some embodiments of the invention, sensor module 20 may be additionally capable of revolving radiation detector 22 about an axis of revolution 25 through an angle of revolution 29. Revolution is produced by a revolution mechanism 27 which may function in a variety of ways as described hereinabove for rotation mechanism 26. According to these embodiments of the invention angle of revolution 29 is included as a component of the orientation of sensor module 20 and is included in output signal 34. Revolution may be employed in the context of any or all of the sensor module 20 configurations described hereinabove and hereinbelow. Revolution may occur, for example, in response to a revolution signal 46 transmitted to sensor module 20 from CPU 42 via channel of communication 48.

According to additional embodiments of the invention, sensor module 20 includes a locomotion device 31 capable of imparting translational motion 33 to module 20 so that the location of module 20 is changed. Locomotion may be initiated, for example, in response to a translational motion signal 46 transmitted to sensor module 20 from CPU 42 via channel of communication 48. According to various embodiments of the invention, locomotion may be used to either permit a single sensor module 20 to operate from multiple locations or to provide angular sensitivity to sensor module 20. In other words, translational motion may be used as a substitute for angular displacement, especially in embodiments which employ at least one radiation shield 36. In embodiments which employs translational motion, translation of a single sensor 20 in a first dimension permits acquisition of a first set of directional information. For example, in the embodiment of system 40 depicted in Figure 4, successive vertical displacement of sensor 20A could be used to determine a first plane in which source 38 resides. Successive horizontal displacement of sensor 20B could be used to determine a second plane in which source 38 resides. Alternately, or additionally, a single sensor 20 may be subject to both vertical and horizontal displacement. Successive vertical and horizontal displacement permits a single sensor 20 to determine two non-parallel planes in which source 38 resides. Concurrent vertical and horizontal displacement along a single line permits a single sensor 20 to determine a single plane in which source 38 resides. Determination of intersection of 2 or 3 or more planes is as determined above. Optionally locomotion and revolution may be employed in the same embodiment of the invention.

Optionally, system 40 further includes an imaging module 50 including an image capture device 56 capable of providing an image signal 52 to CPU 42. Imaging module 50 optionally includes an interface to facilitate communication with CPU 42. CPU 42 is capable of translating image signal 52 to an image of a portion of the body of subject 54. According to various embodiments of the invention, imaging module 50 may rely upon fluoroscopy, MRI,

CT or 2D or multi-plane or 3D angiography. For intracranial procedures, imaging generally need not be conducted concurrently with the procedure. This is because the brain does not shift much within the skull. Images captured a day or more before a procedure, or a few hours before a procedure, or just prior to a procedure, may be employed. According to alternate
5 embodiments of the invention, image data is acquired separately (i.e. outside of system 40) and provided to CPU 42 for alignment.

Alignment methods and the algorithms for anatomical image display and tracking information overlay are reviewed in Jolesz (1997) Radiology. 204(3):601-12. The Jolesz article, together with references cited therein, provides enablement for a skilled artisan to
10 accomplish concurrent display and alignment of image data and tracking data. The Jolesz reference, together with references cited therein, are fully incorporated herein by reference to the same extent as if each individual reference had been individually cited and incorporated by reference.

In an exemplary embodiment of the invention, the location(s) determined by system 40
15 are registered with respect to the image. This may be accomplished, for example by registering system 40 and/or sensors 20 to image capture device 56.

Regardless of which type of sensor module 20 is employed, system 40 may include a display device 43 in communication with CPU 42. Display device 43 may display the image of the portion of the body of the subject with a determined position of the medical device
20 (corresponding to a position of source 38) superimposed on the image of the portion of the body of the subject. The superimposed determined position is optionally represented as a point on display screen 43. Optionally the point is surrounded by an indicator of a desired confidence interval determined by CPU 42. The confidence interval may be displayed, for example, as a circle, as two or more intersecting lines or as one or more pairs of brackets. Alternately, or
25 additionally, display device 43 may display position coordinates of a determined position of the medical device (e.g., corresponding to a position of source 38 at a tip of guidewire).

Display device 43 may be provided with a 3-dimensional angiography dataset from CT, MRI, or 3-D angiography, imaged either during the procedure or prior to the procedure. Appropriate software can be employed to extract a 3-D model of the vasculature from the
30 angiography dataset, and display this model using standard modes of 3-D model visualization. A 3-dimensional graphical representation of the guidewire or catheter can be integrated into the 3-D model of the vasculature and updated with minimal temporal delay based on the position information provided by system 40 to indicate the position of the guidewire or catheter within the vasculature. The entire 3-D model including the vasculature and the catheter can be

zoomed, rotated, and otherwise interactively manipulated by the user during performance of the procedure in order to provide the best possible visualization.

Optionally, system 40 may further include one or more user input devices 45 (e.g. keyboard, mouse, touch screen, track pad, trackball, microphone, joystick or stylus). Input device 45 may be used to adjust an image as described hereinabove on display device 43 and/or to issue command signals to various components of system 40 such as rotation mechanism 26, revolution mechanism 27, locomotion device 31 or image capture device 56.

The invention optionally includes a sensor 20 for determining a plane in which a radiation source resides as depicted in Figure 3 and described hereinabove. Briefly, the sensor 20 includes at least one radiation detector 22, the at least one radiation detector capable of receiving radiation from radiation source 38 and producing an output signal 34. Sensor 20 is capable of rotating radiation detector 22 through a series of positions, each position defined by a rotation angle 32 so that the receiving the radiation from radiation source 38 upon radiation detector 22 varies with rotation angle 32. Rotation is optionally achieved as described hereinabove. A rotation angle 32 which produces a maximum output signal indicates the plane in which radiation source 38 resides.

According to some embodiments of sensor 20, radiation detector 22 includes at least one first radiation detector 22A and at least one second radiation detector 22B and output signal 34 includes a first output signal from first radiation detector 22A and a second output signal from radiation detector 22B.

According to some embodiments of sensor 20, at least one radiation shield 36 is further installed at a fixed angle with respect to detectors 22A and 22B. As a result, a magnitude of the first output signal 34 from the at least one first radiation detector and a magnitude of the second output signal 34 from radiation detector 22B each vary with rotation angle 32 as detailed hereinabove.

A sensor 20 for determining a plane in which a radiation source resides and characterized by at least one radiation shield 36 rotatable about an axis of shield rotation through an angle of shield rotation 32 as described hereinabove in detail (Figure 6B) is an additional embodiment of the invention.

Sensor 20 for determining a plane in which a radiation source resides as depicted in Figure 5 and described hereinabove is an additional embodiment of the invention.

According to alternate embodiments of the invention, a method 400 (Figure 11) of determining a location of a medical device within a body of a subject is provided. Method 400 includes co-localizing 401 a radioactive signal source 38 with a medical device. Co-

localization may be achieved, for example, by providing a device having a radiation source associated therewith or by associating a radiation source with a device.

Method 400 further includes determining 402 a first plane in which the omni directional signal generator resides, further determining 403 a second plane in which the omni directional signal generator resides, calculating 404 a linear intersection of the first plane and the second plane as a means of determining a line upon which the medical device resides.

Method 400 optionally includes further determining 405 at least one additional plane in source 38 resides.

Method 400 optionally includes calculating 406 a point of intersection of the first plane, the second plane and the at least one additional plane as a means of determining a location of the medical device.

Optionally, method 400 is successively iterated 408 so that a series of location are generated to track an implanted medical device in motion. Calculated locations may be displayed 410 in conjunction with anatomical imaging data if desired.

The various aspects and features of system 40 and/or sensors 20 described in detail hereinabove may be employed to enable or enhance performance of method 400.

System 40 and method 400 may employ various mathematical algorithms to compute the location of source 38. One example of an algorithm suited for use in the context of some embodiments of the invention calculates the position of source 38 from sensor output signal 34, sensor position, and sensor orientation (i.e. rotation angle 32) of three sensors as follows:

- 1) the plane defined by each sensor module 20 is calculated using an equation of the form

$$Ax+By+Cz=D$$

- 2) the coefficients A,B,C, and D are calculated as follows:

- a. Three non-collinear points are defined within sensor 20's internal reference frame.
- b. These three points are then shifted by the position of sensor 20 and rotated by the sensor orientation. This defines the plane in which source 38 would lie if output signal 34 was zero.
- c. These three points are then rotated about the axis of rotation angle 32 of sensor 20 by rotation angle 32 indicated by output signal 34. This defines the plane in which source 38 lies as measured by a particular sensor 20.
- d. Using the x,y,z coordinates of the three points, $x_1, y_1, z_1, x_2, y_2, z_2, x_3, y_3, z_3$ in the following equations, A, B, C, and D are calculated as follows:

- i. $A = y_1(z_2 - z_3) + y_2(z_3 - z_1) - y_3(z_1 - z_2)$
- ii. $B = z_1(x_2 - x_3) + z_2(x_3 - x_1) + z_3(x_1 - x_2)$
- iii. $C = x_1(y_2 - y_3) + x_2(y_3 - y_1) + x_3(y_1 - y_2)$
- iv. $D = x_1(y_2 * z_3 - y_3 * z_2) + x_2(y_3 * z_1 - y_1 * z_3) + x_3(y_1 * z_2 - y_2 * z_1)$

- 5 3) Calculation of A, B, C, and D for each of three sensors 20 produces a system of three equations in three unknowns:

$$\begin{bmatrix} A1 & B1 & C1 \\ A2 & B2 & C2 \\ A3 & B3 & C3 \end{bmatrix} \begin{bmatrix} x \\ y \\ z \end{bmatrix} = \begin{bmatrix} D1 \\ D2 \\ D3 \end{bmatrix}$$

This system of equations can be solved to provide an exact solution for (x,y,z) (or part of the vector), the point of intersection of the three planes, which is the position of the source 38.

Use of additional sensors 20 improves the accuracy by averaging the errors in the individual sensors, and may also provide a means of estimating the accuracy of the position measurement by indicating the extent to which the sensors agree with each other.

When 4 or more sensors are used, the algorithm is as follows:

Steps 1 and 2 above remain the same – the equation of the plane indicated by each sensor is calculated. Step 3 is modified as follows:

- 20 3) Once A, B, C, and D have been calculated for each of the sensors an over-determined system of more than three equations in three unknowns results;

$$\begin{bmatrix} A1 & B1 & C1 \\ A2 & B2 & C2 \\ A3 & B3 & C3 \\ \vdots & \vdots & \vdots \end{bmatrix} \begin{bmatrix} x \\ y \\ z \end{bmatrix} = \begin{bmatrix} D1 \\ D2 \\ D3 \\ \vdots \end{bmatrix}$$

This over-determined system can be solved in a least square sense using methods familiar to those skilled in the art in order to obtain the best solution for (x,y,z), which is the most likely position of the tracked element. There is generally no exact solution due to the error in the sensor outputs, there may be no single point through which all of the planes pass.

In order that the least square solution may be based on the error defined by the Euclidian distance between each plane and the solution for (x,y,z), it is necessary to

scale all of the coefficients defining each plane by the lengths of their respective Normal vectors (the Normal vector is the vector defined by (A,B,C)). This is done by dividing A, B, C, and D by $\sqrt{A^2 + B^2 + C^2}$ before performing the least square solution.

- 5 4) The Euclidian distance between each of the planes and the calculated position can be used as a measure of the accuracy of the position measurement. Once the coefficients have been scaled by the length of the Normal vector, this distance can be calculated for each sensor as $Ax+By+Cz-D$. The mean value of the distances from each plane to the calculated position gives a measure of the extent to which all of the sensors agree on the
10 position that was calculated.

Overdetermined systems of equations may be solved using least square solution algorithms. Suitable least square algorithms are available as components of commercially available mathematics software packages.

Optionally, other methods of solving equation sets as known in the art are used. Optionally,
15 instead of a set of equations, other calculation methods are used, for example, neural networks, rule based methods and table look up methods in which the signals from the sensors are used to look-up or estimate a resulting position. In systems where the sensors move linearly, other solution methods may be used, for example, translating linear positions of the sensors into spatial coordinates of the source.

20 In order to increase the accuracy and performance of system 40 and method 400, advance calibration may optionally be performed. The position and orientation of each of the sensor modules 20 can be calibrated instead of relying upon values based on the mechanical manufacturing of the system. The calibration procedure involves using system 40 to measure the 3-dimensional position of a source 38 at a number of known positions defined to a high
25 degree of accuracy. Since the position of source 38 is known, the equations normally used to calculate the positions (described above) can now be used with the sensor positions and orientations as unknowns in order to solve for these values. Various minimization procedures are known in the art. The number of measurements needed to perform such a calibration may depends on the number of sensor modules 20 in system 40, since it is useful to make enough
30 measurements to provide more equations than unknowns. This calibration procedure also defines the origin and frame of reference relative to which system 40 measures the position of the source, and can therefore provide alignment between the tracking system and another system to which it is permanently attached, such as a fluoroscopy system or other imaging system.

In an exemplary embodiment of the invention, once a position of the source is known, the sensors can remain aimed at the source and not change their orientation. Optionally, if the source moves, determined for example, by a significant change in detected radiation (e.g., a drop of 30%, 50%, 70%, 90% or a greater or intermediate drop), the sensor is moved to scan a range of angles where the source is expected to be in. Optionally, the sensor generates a signal indicating on which side of the sensor the source is located, for example as described below. Optionally, the range of scanning depends on an expected angular velocity of the source, for example, based on the procedure, based on the history and/or based on a user threshold. If scanning within the range fails, the range is optionally increased.

Optionally, if multiple target sources are provided (e.g., ones with different count rates and/or different energy of emission), the sensors jump between target angles. Optionally, a steady sweep between a range of angles encompassing the two (or more) sources is provided. Optionally, sweeping is provided by ultrasonic or sonic vibrations of the sensor or part thereof, for example, comprising a range of angles 1, 5, 10, 20, 50 or more times a second. Optionally, the amplitude of the vibration determines the range of angles. Optionally, the sensors or sensor portion is in resonance with one or more vibration frequencies.

Optionally, scanning of the sensors, at least in a small range of angles, such as less than 10 or less than 5 or less than 1 degree, is provided even when the sensor is locked on a target source.

The tracking accuracy of system 40 using Iridium-192 as source 38 as described hereinabove has been evaluated only by computer simulation. The simulation is a model of the random distribution of gamma photons emitted by a source 38 within a model head and absorbed by the photon-sensitive elements 22 in a compound differential sensor unit 20 of the type illustrated in Figure 5. According to the simulation, radiation detector 22 of sensor module 20 rotates so that a new rotation angle 32 is defined every time a photon is absorbed by detector 22. If the photon is absorbed by a positive radiation detector 21 then radiation detector 22 of sensor module 20 rotates in the positive direction, and if it is absorbed by a negative sensor 23 then radiation detector 22 of sensor module 20 rotates in the negative direction. Total output signal 34 of sensor module 20 is its average orientation during the sample time.

According to the simulation, performance is defined by two parameters, however other parameters may be used in a practical system:

- 1) The Root Mean Square (RMS) error when the target is stationary

- 2) The time to indicate a 9mm change in calculated location after a 10mm change in actual location of source 38.

The following parameter values are fixed in the simulation:

- 1) Distance from the source to the sensor = 25cm (worst case distance)
- 2) Source distance for which sensor is geometrically optimized = 25cm
- 3) Width of photon-sensitive surface in each sub sensor = 2mm (18 in Figure 5)
- 4) Sensor length = 10cm (14 in Figure 5)
- 5) Height of dividing walls between sensors = 5cm (35 in Figure 5)
- 6) Width of dividing walls at their base = 4mm (37 in Figure 5)
- 7) Number of subsensors defined by walls in the compound sensor = 7 (36 in Figure 5)
- 8) Sensor sensitivity (fraction of incoming gamma rays which are detected) = 0.3

The simulation evaluated and optimized the following parameters with respect to influence on performance:

- 1) Rotation magnitude per absorbed photon (Figures 7a and 7b)
- 2) Sample time (Figures 8A and 8B)
- 3) Photons per second (source activity level) (Figures 9A and 9B)
- 4) Overall tracking accuracy (Figures 10a and 10b)

The simulation determined that as rotation per photon impact increases, response time is improved (Figure 7a). However, as rotation per photon impact increases, RMS position error also increases (Figure 7b). There is clearly a trade-off between latency and accuracy. This parameter can be modified in real-time in order to optimize the trade-off using a motion detection algorithm as described hereinbelow.

The simulation determined that sample time no significant impact on latency or accuracy (Figures 8A and 8B). This is because for small values of rotation per impact, the number of impacts per sample has minimal effect on accuracy and only determines the latency (the total amount of rotation per sample). However, if the number of impacts per sample is reduced as a result of a reduction in the sample time, then the reduction in sample time exactly compensates for the reduced response per sample leaving the latency unchanged.

Radioactivity (number of photons emitted per second) has a very slight effect on accuracy, improving accuracy only by a factor of 2 as the activity increases from 0.01mCi up to 0.5mCi (Figure 9B). It has a drastic effect on response time at low activity levels (Figure 9A) where

there simply are not enough photons to induce rapid rotation, however at activity levels above 0.1mCi there is minimal improvement with increased activity level. Optimization of this trade-off between latency and accuracy (see below) is achieved with 0.05mCi. This specific activity provides a good compromise between performance and radiation dose, providing a performance suitable for a typical medical application without imposing a safety risk to the patient or doctor.

In order to optimize the tradeoff between accuracy and latency a motion detection algorithm was employed to increase the rotation per photon during motion of tracked source 38. This decreased latency time and increased accuracy. In the simulation, the percentage of photons hitting receiving elements 22 classed as positive 21 versus those classed as negative 23 was used as an indication of motion of tracked source 38. As the percentage moved farther away from 50% the rotation per photon was increased, reducing latency at the expense of accuracy during motion. In other words, system 40 begins by moving towards an estimated target rotation angle 32 in large steps. As estimated target rotation angle 32 is approached, the size of the steps is decreased. If target rotation angle 32 is passed, a small compensatory step in the opposite direction is employed. Results are summarized graphically in Figures 10a and 10b. Briefly, the RMS error of system 40 tracking a moving source 38 is 0.71 mm on average. Location of a stationary source 38 by system 40 produces an rms error of 0.62 mm.

In summary, the simulation results indicate that with an activity of 0.05mCi of ¹⁹²Ir, compound differential sensors of the type illustrated in Figure 5, and a motion detection algorithm which trades-off latency against accuracy, system 40 can achieve overall accuracy of approximately 1mm RMS.

Simulated sensitivity of sensor module 20 to changes in rotation angle 32 is illustrated in Figure 12 which is a plot of output signal 34 as a function of rotation relative to target rotation angle 32 for a sensor of the type indicated in Figure 5. The graph was produced using the formula:

$$\text{Total Output 34} = A / (A+B)$$

Where A is the sum of all right side sensors 21; and

B is the sum of all left side sensors 23 and B

The total range of output 34 (Y axis) from sensor 20 was arbitrarily defined as being in a range from 0 to 1. On the X axis, 0 indicates the angle of rotation 32 which indicates the direction of source 38. The total rotational range of sensor 20 was ± 32 milliradians from this target rotation angle 32. Deviation of more than 32 milliradians away from target rotation angle 32 produced an output 34 of either 0 or 1, indicating the direction of rotation for a return to

target rotation angle 32, but not the amount of rotation to reach target rotation angle 32. When output 34 is 0 or 1, the only conclusion that can be drawn about deviation from target rotation angle 32 is that it is greater than 32 milliradians in the indicated direction.

The graph of Figure 12 depicts output 34 for target rotation angle 32 as the middle of the dynamic range (0.5). Therefore, if output 34 is 0.6, a correctional rotation of 10 milliradians in the plus direction is indicated to achieve target rotation angle 32. An output 34 of 0.6 indicates a correctional rotation with the same magnitude (10 milliradians), but in the minus direction. Another way of depicting the same information would be to indicate a total dynamic range of +0.5 to -0.5 on the Y axis. This middle of the range could be zero, with one direction being positive and the other negative, or it can be any arbitrary number, with one direction being higher and the other lower.

As illustrated in Figure 12, at target angle 32 simulated sensitivity of sensor 20 to rotation is approximately 1% of the dynamic range per milliradian of rotation.

This 1% sensitivity per milliradian is sufficient to provide the desired accuracy (1mm rms), using a 5 cm X 10 cm sensor module 20 with shields 36 having a height 35 of 5cm interspersed between radiation detectors 22 and located 25cm from source 38 with an activity of 0.65mCi. Adjusting accuracy parameters, increasing the size of detectors 22, reducing the distance between sensor 20 and source 38 and increasing the activity of source 38 could each serve to reduce the level of directional sensitivity desired of sensor 20.

Simulation results (not shown) using a sensor 20 of the type shown in Figure 6A were similar to those described hereinabove.

System 40 and/or sensors 20 rely upon execution of various commands and analysis and translation of various data inputs. Any of these commands, analyses or translations may be accomplished by software, hardware or firmware according to various alternative embodiments. In an exemplary embodiment of the invention, machine readable media contain instructions for transforming output signal 34 from one or more sensor modules 20 into position co-ordinates of source 38, optionally according to method 400. In an exemplary embodiment of the invention, CPU 42 executes instructions for transforming output signal 34 from one or more sensor modules 20 into position co-ordinates of source 38, optionally according to method 400.

According to an exemplary embodiment of the invention a trackable medical device is manufactured by incorporating into or fixedly attaching a detectable amount of a radioactive isotope to the medical device. The radioactive isotope may or may not have a medical function according to various embodiments. Optionally, the radioactivity of the isotope has no medical

function. Optionally, the radioactive isotope may be selected so that it can be used in the body without a protective coating without adverse reaction with tissue. In an exemplary embodiment of the invention, the detectable amount of isotope is in the range of 0.5mCi to 0.001mCi. Use of isotope source 38 with an activity in the lower portion of this range may depend on lower speeds of the device, sensitivity of detector(s) 22, distance from sensor 20. Optionally, at least 1, optionally at least 5, optionally at least 10, optionally at least 100 detectable counts per second are produced by the incorporated radioactive isotope.

In the description and claims of the present application, each of the verbs "comprise", "include" and "have" as well as any conjugates thereof, are used to indicate that the object or objects of the verb are not necessarily a complete listing of members, components, elements or parts of the subject or subjects of the verb.

The present invention has been described using detailed descriptions of embodiments thereof that are provided by way of example and are not intended to necessarily limit the scope of the invention. The described embodiments comprise different features, not all of which are required in all embodiments of the invention. Some embodiments of the invention utilize only some of the features or possible combinations of the features. Variations of embodiments of the present invention that are described and embodiments of the present invention comprising different combinations of features noted in the described embodiments can be combined in all possible combinations including, but not limited to use of features described in the context of one embodiment in the context of any other embodiment. The scope of the invention is limited only by the following claims.